UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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BETH FORMAN, individually and as Executrix of the Estate of John Napolitano,

Plaintiff,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

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MEMORANDUM OF DECISION AND ORDER

09-CV-4678 (ADS)(WDW)

APPEARANCES:

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SPATT, District Judge.

On March 8, 2011, the Court issued a memorandum of decision and order addressing a number of Daubert motions by the parties, including a motion by defendant Novartis Pharmaceuticals Corporation ("NPC" or "Novartis") to exclude the expert testimony of Dr. Suzanne Parisian in the above-captioned matter, Beth Forman, individually and as Executrix of the Estate of John Napolitano v. Novartis Pharmaceuticals Corporation, 09-CV-4678 ("the Forman case") and in Samuel Deutsch, individually and as Administrator of the Estate of Helene Deutsch v. Novartis Pharmaceuticals Corporation, 09-CV-4677 ("the Deutsch case"). See Deutsch v. Novartis Pharmaceuticals Corp., 2011 WL 790702 (E.D.N.Y. 2011) ("March 8, 2011 Order"). In the March 8, 2011 Order, the Court granted in part and denied in part NPC's motion to exclude Dr. Parisian's testimony, and reserved decision on the admissibility of certain opinions pending the outcome of a Daubert hearing. On June 20, 2011, the parties in the Deutsch case entered into a stipulation of settlement on the record. Insofar as the Court is entering this order after the date of the settlement in the Deutsch case, this decision is only applicable to the Forman case.

The core of Dr. Parisian's proposed testimony as set forth in her report is her opinions on the reasonableness of NPC's conduct in complying with FDA regulations and interacting with the FDA. In the March 8, 2011 Order, the Court found both that Dr. Parisian was qualified to offer these opinions and "that Dr. Parisian's specialized knowledge in the interplay between the FDA and pharmaceutical companies in obtaining drug approval, developing and approving labels and warnings, and in conducting and monitoring clinical trials would be helpful to the trier of fact in providing a opinion on the actions by Novartis from a regulatory perspective." March 8, 2011 Order at *43. However, based on the structure of Dr. Parisian's report, the Court was

unable to ascertain whether Dr. Parisian utilized a reliable methodology in forming her opinions. In addition, the Court noted that Dr. Parisian's report consistently mixed potentially admissible opinions with inadmissible opinions, and was concerned that, if permitted to testify, Dr. Parisian would be unable to adequately separate the two areas so as to avoid prejudice to NPC. Thus, the Court determined that a Daubert hearing was necessary to determine whether: (1) Dr. Parisian employed a reliable methodology and (2) Dr. Parisian can testify as to her opinions within the confines of certain limitations so as to avoid prejudice to Novartis. Id. at *45.

The Court held the above-referenced Daubert hearing on April 11, 2011 and May 2, 2011. At the conclusion of the hearing, the Court directed both parties to submit proposed findings of fact and conclusions of law. Notably, this was not an opportunity to seek reconsideration of the Court's prior order, nor to present new arguments for exclusion—e.g., federal preemption of evidence relating to FDA regulations. The purpose of the Daubert hearing was solely to determine whether: (1) Dr. Parisian employed a reliable methodology and (2) Dr. Parisian can testify as to her opinions within the confines of certain limitations so as to avoid prejudice to Novartis. Id. at *45. Based on Dr. Parisian's testimony at the Daubert hearing, in conjunction with the information in her report, the Court finds that Dr. Parisian's methodology is reliable and that there is no risk of prejudice to NPC by permitting her testimony.

To determine whether a proffered expert's testimony is reliable, the Court "must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district court's belief as to the correctness of those conclusions." Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 266 (2d Cir. 2002). "An expert is permitted to draw a conclusion from a set of observations based on extensive and specialized experience." In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 190 (S.D.N.Y. 2009); see

also Amorgianos, 303 F.3d at 256 (("[I]n analyzing the admissibility of expert evidence, the district court has broad discretion in determining what method is appropriate for evaluating reliability under the circumstances of each case.").

Here, Dr. Parisian's report and testimony reveal that the information underlying her conclusions were drawn from her review of certain NPC regulatory filings, internal NPC documents, and medical literature. Furthermore, as Dr. Parisian testified, she reached the opinions expressed in her report by taking this information and applying the relevant FDA regulations and procedures. As her testimony at the hearing clarified, this is the same methodology that she applied while working at the FDA. Thus, the Court finds that Dr. Parisian's methodology is reliable and is permitted to render opinions on "the reasonableness of Novartis' conduct in its interactions with the FDA and compliance with FDA regulations, including Novartis' interactions with FDA with respect to labels and warnings, and FDA regulations and interactions with companies regarding clinical trials." March 8, 2011 Order at *78.

In addition, the Court found that Dr. Parisian testified in the manner expected of a professional and did not exhibit any behavior that would lead this Court to question her ability to testify within the confines of her expert report and the limitations on her testimony as set forth in the March 8, 2011 Order. However, the Court notes that at the Daubert hearing, the Court permitted the parties to elicit testimony from Dr. Parisian on issues of causation when discussing certain articles or the Aredia and Zometa clinical trials, despite the fact that the Court explicitly precluded such testimony as outside the scope of Dr. Parisian's expertise in the March 8, 2011 Order. This testimony was permitted solely for the benefit of the Court in the context of the Daubert hearing, and the Court's allowance of this testimony, or any other opinions that were

otherwise precluded under the March 8, 2011 Order, does not constitute a reversal of those holdings.

Finally, although NPC argues that this Court should follow the recent decision by Judge Brian M. Cogan in another Aredia/Zometa case, Hogan v. Novartis Pharmaceutical Corporation, No. 06-CV-260, 2011 WL 1533467 (E.D.N.Y. April 24, 2011), where Judge Cogan excluded Dr. Parisian's testimony in its entirety, the Court finds Hogan to be distinguishable. In Hogan, the plaintiff's claims in the complaint were grounded in the state common-law and made no reference to the FDA. In addition, the plaintiff acknowledged that evidence that NPC did not comply with FDA regulations, including the testimony of Dr. Parisian, was mostly necessary to rebut NPC's anticipated defense based on FDA approval of the Zometa label and the lack of FDA action against NPC for the Zometa warnings. However, Judge Cogan noted that, in the parties' joint pre-trial order, NPC had not presented any defense based on the FDA. Insofar as the plaintiff had not included FDA compliance in its complaint, and NPC had not included FDA approval as a defense in the joint pre-trial order, Judge Cogan held that:

> Plaintiff cannot have her cake and eat it too; she cannot bring common law claims not grounded in FDA regulations only to present an expert to opine on whether defendant violated those regulations. By the same token, the Court will not permit defendant to litigate the case in the shadow of the FDA. . . .
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> . . . [A]ny evidence or testimony discussing the FDA, its regulations, and upcoming meetings, will not be admitted without independent probative value; evidence that reveals nothing more than responsiveness to the FDA is irrelevant.

2011 WL 1533467, at *2. As a result, Judge Cogan precluded Dr. Parisian's testimony with respect to the FDA, apparently not based on a lack of qualifications or improper methodology, but because it was not relevant in the case before him.

By contrast, both the Plaintiff and NPC have affirmatively asserted that NPC's compliance, or lack of compliance, with FDA regulations is persuasive evidence of the NPC's reasonableness and the adequacy of the Aredia and Zometa warnings. Accordingly, absent any representation by the parties to the contrary, the FDA, and NPC's compliance with FDA regulations are issues that are relevant to the instant litigation**.** Therefore, so is Dr. Parisian's testimony.

SO ORDERED.
Dated: Central Islip, New York
June 22, 2011

/s/ Arthur D. Spatt
ARTHUR D. SPATT
United States District Judge